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Dr. Scott A. Masten  
Office of Chemical Nomination and Selection  
NIEHS/NTP  
P.O. Box 12233  
MD A3-07  
Research Triangle Park, NC 27709

**Re: Comments Relating to Sodium Metasilicate [6834-92-0], a Substance  
Nominated to the National Toxicology Program and Recommended for  
Study by the ICCEC 67 Fed. Reg. 40329-40333 (June 12, 2002)**

Dear Dr. Masten:

The PQ Corporation, formerly the Philadelphia Quartz Company, is a leading manufacturer of sodium metasilicate products. Sodium metasilicate is widely used as an alkaline builder in industrial detergents, as a food additive, and for water treatment.

We were surprised and puzzled to learn that sodium metasilicate had been nominated to the NTP with recommendations for subchronic inhalation studies and respiratory hypersensitivity studies because to the best of our knowledge all sodium metasilicate products marketed in the United States and elsewhere are entirely nonrespirable. They are granular products, that are screened during production typically such that they pass through screens of 20 meshes to the inch and are held by screens of 48 meshes to the inch. Therefore, the large, dense, granules, which comprise sodium metasilicate, cannot become entrained in the air, and cannot be inhaled.

It is impossible for commercial sodium metasilicate to even be tested as recommended. Even if some method were developed to suspend the large granules of sodium metasilicate in air, it would be physiologically impossible for animals to breathe them. Thus, if sodium metasilicate were to be tested by inhalation it would be necessary to grind it to a fine powder which does not model exposure to the commercial product. Moreover, inhalation testing ground sodium metasilicate would present considerable technical difficulties in conducting inhalation tests. Anhydrous sodium metasilicate is hygroscopic and also absorbs carbon dioxide from the atmosphere. Air for inhalation studies using fine particle of sodium metasilicate would therefore have to have water and CO<sub>2</sub> removed; further deviating from conditions that would model real world occupational exposure.

A second objection to the listing is that NTP appears to have mistaken a positive result in a *topical* mouse ear hypersensitivity study as new information about sodium metasilicate

which may be indicative of hitherto unknown hazard to workers who are exposed to sodium metasilicate. This is not the case. Contact allergic reaction to soluble silicates is known to occur, but it is very rare in humans.<sup>1</sup> Hypersensitivity to *inhaled* sodium metasilicate apparently does not occur at all because virtually all metasilicate use is of the granular nonrespirable material, and even in manufacturing operations, inhalation exposure to unscreened sodium metasilicate is self-limiting. The primary irritant effects of sodium metasilicate's alkalinity make respirable particles obnoxious, if not intolerable, in the atmosphere. This was recognized back in the 1930s when metasilicate products were first commercially developed. It is the reason all commercial sodium metasilicate products are screened to produce a nonrespirable product. We also note that the number of workers in plants where sodium metasilicate is manufactured (and where unscreened sodium metasilicate can be present in the workplace) is less than 200 nationwide.

Although the absence of evidence is not necessarily evidence of absence, we note that sodium metasilicate has been produced and used in the United States for over seventy-five years. It is unquestionably a large volume product. By 1978, its production rate was hundreds of thousands of tons each year which was on the order of a kilogram per person.<sup>2</sup> Its production has continued to increase since then. Thousands of workers use it every day, albeit as nonrespirable granules. If hypersensitivity were not exceedingly rare, there would certainly be more documentation in the medical literature than the single case reported in 1982 by *Tanaka, et al.*, previously cited.

The utility of a subchronic inhalation study of sodium metasilicate is also called into question by the fact that inhaled soluble silicates rapidly dissolve in the lungs, pass into the blood and are rapidly excreted in the urine.<sup>3</sup> Their urinary excretion half-life is approximately 24 hours. The proposed subchronic inhalation testing would likely therefore model serial acute exposures rather than cumulative subchronic exposures, unless large doses were administered. If high doses were used, it is hard to conceive how the acute lethal effects of alkalosis could be avoided. We note that if the alkalinity of sodium metasilicate were to be neutralized to physiological pH, the sodium metasilicate would cease to exist. It would be transformed into a different substance, amorphous silica, for which there is a copious literature of inhalation studies. These were reviewed approximately five years ago for an IARC Monograph.<sup>4</sup>

We also call NTP attention to the fact that the safety of soluble silicates, including sodium metasilicate has been extensively reviewed by multiple expert panels of toxicologists because of the extensive use of these chemicals in food and consumer products. Until NTP's nomination of sodium metasilicate, the conclusions of expert toxicological panels has invariably been that there is sufficient information to conclude that sodium metasilicate does not present unreasonable risk to human health. Sodium metasilicate is regarded by FDA as a

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<sup>1</sup> Tanaka T, Miyachi Y, Horio T., Ulcerative contact dermatitis caused by sodium silicate. Coexistence of primary irritant contact dermatitis and contact urticaria. *Arch Dermatol* 1982 Jul;118(7):518-20

<sup>2</sup> Weissler, Alfred, "Monograph on Sodium Metasilicate" NTIS publication PB-287 766 (prepared for the U.S. Food and Drug Administration Bureau of Foods) 3 May, 1978, p. 19.

<sup>3</sup> Michon, R.; Sue, P.; Merinis, J., "Hygiene Du Travail.-Metabolisme de la silice et des silicates inhalés par l'animal, suivi à l'aide de <sup>31</sup>Si." *Comptes Rendus*, 243, 1956, p. 2194

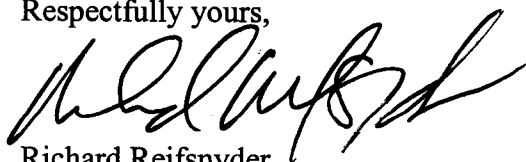
<sup>4</sup> "Silica, Some Silicates, Coal Dust, and para-Aramid Fibrils, IARC Monographs Volume 68, p. 41-242

GRAS (Generally Recognized As Safe) Substance. Its safety for food-related uses was reviewed for FDA Select Committee on GRAS Substances by FASEB in 1981<sup>5</sup>. Their report concluded "There is no evidence in the available information on sodium metasilicate that demonstrates or suggests reasonable grounds to suspect a hazard to the public when it is used as a food ingredient in the manner now practiced at levels that are now current or that might reasonably be expected in the future." It is also relevant to note that the available toxicological information on detergent sodium silicates, including sodium metasilicate, was reviewed by an expert toxicology task force of Great Lakes Science Advisory Board of the International Joint Commission, an intergovernmental body composed of representatives of the United States and Canada who administer a treaty between the U.S. and Canada to preserve the quality of the Great Lakes. U.S. Representatives included representatives from the National Center for Toxicological Research, FDA, and the National Academy of Sciences. An adjunct member was Dr. Raymond Shapiro, Assistant Director for Toxicology Coordination, NIEHS. Their report states, "In man, except for non-specific irritation or corrosion of skin, cornea and mucous membranes, no apparently toxic actions of sodium metasilicate are recognized." (citations omitted)<sup>6</sup>

In conclusion, sodium metasilicate is inappropriate for listing as a substance recommended for subchronic inhalation and respiratory hypersensitivity study because it is nonrespirable, that contact sensitization is a known, but exceedingly rare in humans, that inhalation sensitization does not occur because inhalation exposure rarely occurs and is self-limiting if it does occur, that inhaled sodium metasilicate is rapidly excreted, and that the safety of sodium metasilicate has been repeatedly reviewed and affirmed by expert panels of governmental toxicologists.

Thank you for the opportunity to comment on this nomination. If you have questions regarding anything discussed in this letter or we can assist NTP in its efforts with regard to sodium metasilicate, please let us know.

Respectfully yours,



Richard Reifsnyder  
Technical Service Manager  
Industrial Chemicals

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<sup>5</sup> Life Sciences Research Office, Federation of American Societies for American Biology, "Evaluation of the Health Aspects of Sodium Metasilicate and Zinc Metasilicate as Food Ingredients," SCOGS-II-20 (1981), p. 13.

<sup>6</sup> Task Force on the Health Effects of Non-NTA Detergent Builders, "Report to the Great Lakes Science Advisory Board of the International Joint Commission on the Health Implications of Non-NTA Detergent Builders," (October 1980, Revised March 1981) p. 45.